BJJ&A
Total Water Treatment
Bob J. Johnson & Associates, Inc.

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JUL - 7 2006

Premarket Notification 510(K) Summary

Water Purification Components for Hemodialysis
Regulatory Classification: 21 CFR 876.5665
Class II
Product Code: 78 FIP

Note: In this summary the work "component" refers to an individual part of a water treatment system. Example: the activated carbon exchange tank or deionization exchange tank. The word system refers to the water purification plant as a whole. Example: the water softener, activated carbon filter, reverse osmosis, storage tank, ultrafiltration, ultraviolet sterilizer, and pumping systems. We are claiming substantial equivance to components.

Bob J. Johnson & Assoc., Inc. (BJJ&A) is applying for a 501(k) premarket notification for our "Water Purification Components for Hemodialysis". The following is a summary of our submission document. The regulatory classification is class II CFR 876.5665(a), Product Code 78 FIP. The device we are claiming substantial equivalence to is marketed by AmeriWater Company. The registration number for this device is K99159, AmeriWater Company. Purification System. Regulatory Class: II, 21 CFR 876.5665/Procode: 78 FIP.

The BJJ&A water purification component for hemodialysis will be used with a hemodialysis system. The Water purification system will remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate, bicarbonate, acetate and sterilant for dialyzer reprocessing.

The purified water will also be used in the equipment disinfection process, equipment rinsing and any other application the clinic/customer deems appropriate. This system will meet all the requirements put forth by the United States Food and Drug Administration (FDA) and the Association for the Advancement of Medical Instrumentation (AAMI) and any other laws that may apply.

The BJJ&A water purification components, both activated carbon filtration and deionization, utilize no new water purification techniques, The predicate device components we are

claiming SE to, utilizes the exact same water purification principles. The following is a comparison summary of the BJJ&A water treatment components and the predicate device.

Deionization tanks from both BJJ&A and AmeriWater are utilized to remove dissolved solids from the water. Both utilize mixed bed resin, consisting of anion and cation resin, to remove the charged particles from the water. Both utilize parts and materials which are "NSF" and/or FDA approved.

Activated carbon filtration is utilized by both BJJ&A and AmeriWater to filter out chlorine and chloramines from the water, BJJ&A uses carbon filter made from materials, which are FDA or NSF approved. Both companies use two carbon filters in a series configuration. A minimum total contact time of 10 empty bed contact time minutes are incorporated into both designs as recommended by the FDA for chlorine and chloramines removal. Both BJJ&A and AmeriWater recommended the chlorine and chloramine levels be checked before each patient shift. Both companies recommend hard plumbed bypass piping of the carbon tanks not be allowed on either component. Both components will utilize an activated carbon with an Iodine number of 900 or greater. BJJ&A always recommends using a dual carbon filter in series in every dialysis water system installed, including single patient systems.

The devices that BJJ&A are seeking 510K for are:

SECTION F	PRODUCT INFORMATION - APPLICATION TO ALL APPPLICATIONS		
Common or usual name or classification	Water Purifcation Components for Hemodialysis		
	Trade or Proprietary or Model Name for This Device		Model Number
1	.25 cu ft Activated Carbon Exchange Tank	1	BJAC-.25
2	.54 cu ft Activated Carbon Exchange Tank	2	BJAC-.54
3	1.2 cu ft Activated Carbon Exchange Tank	3	BJAC-1.2
4	2.1 cu ft Activated Carbon Exchange Tank	4	BJAC-2.1
5	3.6 cu ft Activated Carbon Exchange Tank	5	BJAC-3.6
6	.25 cu ft Deionization Exchange Tank	6	BJDI-.25
7	.54 cu ft Deionization Exchange Tank	7	BJDI-.54
8	1.2 cu ft Deionization Exchange Tank	8	BJDI-1.2
9	2.1 cu ft Deionization Exchange Tank	9	BJDI-2.1
10	3.6 cu ft Deionization Exchange Tank	10	BJDI-3.6

Included in this document is labeling that is applied to the components of the water purification system for hemodialysis. AAMI water purification standards are also included.

With an actual water quality analysis and Total Organic Carbon analysis from existing water purification components for dialysis. Dimensional drawing and product specification sheet are included in this submittal along with owner's manual for each of the components models.

In summary, the BJJ&A water purification components and the AmeriWater predicate device components are very similar to one another. The core water purification components and technology are exactly the same.

Note: The Renal Care Facilities will supply their own water purification system, which consists of reverse osmosis system, ultra-filtration rack, water softeners, and storage tanks. BJJ&A will only be providing the activated carbon and deionization components to their systems.

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Jon E. Hulsey
President & CEO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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JUL - 7 2006

Mr. Jon E. Hulsey
President & CEO
Bob J. Johnson & Associates, Inc.
16420 West Hardy Road, Suite 100
HOUSTON TX 77060

Re: K060942
Trade/Device Name: Carbon Exchange Tank Series BJAC and DI Exchange Tanks Series BJDI
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: March 31, 2006
Received: April 6, 2006

Dear Mr. Hulsey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060942

Device Name: Carbon Exchange Tank Series BJAC and DI Exhange Tanks Series BJDI

Indications For Use:

These Water Purification Devices are intended to be used as components of a water purification system to remove organic and inorganic substances from water that is used to dilute dialysis concentrate to form dialysate and to produce purified water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection.

Note: The Renal Care Facilities will supply their own water treatment system, which consists of water softeners, ultra-filtration, reverse osmosis system, alarms, monitors, tanks, and pumping stations. Bob J. Johnson & Associates will only be providing the activated carbon and deionization components to their systems.

Prescription Use __XX_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060942